Remarks

Claims 1-49 were pending in this application. Claims 1, 8, 28, 39 and 46 have been amended. Claims 5, 27, 43, 47 and 48 have been cancelled. Claims 50-55 have been added. In the Office Action, the Examiner has rejected the claims 1, 3, 5, 8-14, 20, 28, 30, 32, 35-39, 41, 43, and 46-49 under 35 U.S.C. §102(b) as anticipated by or in the alternative, under 35 U.S.C. §103(a) as unpatentable over U.S. Patent 4,964,261 to Benn (hereinafter "Benn") in view of U.S. Patent 1,931,911 to White (hereinafter "White"). Claims 4, 15-19, 21, 22, 31 and 42 are rejected under 35 U.S.C. §103(a) as being unpatentable over Benn. Claims 2, 6, 29, 33, 40 and 44 are rejected under 35 U.S.C. §103(a) as being unpatentable over Benn in view of U.S. Patent 4,176,153 to Weiler et al. (hereinafter "Weiler"). Claims 7, 34 and 45 are rejected under 35 U.S.C. §103(a) as being unpatentable over Benn and Weiler in view of U.S. Patent 3,382, 642 to Shaw (hereinafter "Shaw"). Claims 23-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Benn in view of U.S. Patent 5,673,731 to Green et al. (hereinafter "Green").

Applicant has amended Claims 1, 8, 28, 39 and 46 to clarify how the container is held and clarify the location of the pressure application. As discussed below, new Claims 50-55 have been added.

As an initial matter, it should be noted that the present invention is directed to a method of filling a container for a delivery device for introducing a fluidic substance to a patient. Such systems are desirable to control the volume and characteristics of the fluid in the container. Additionally, it is desirable to have a system that controls the fluidic levels and properties within the container. The container has a flexible portion and a rigid portion. The method and device as now claimed includes a pressurization and sealing method which controls these parameters by applying a controlled pressure environment to at a portion of the exterior of the flexible component by subjecting the exterior of the container to **a controlled pressure environment which is formed by at least a portion of the container itself.**

Claim Rejections under 35 USC 102

In the Office Action, the Examiner has rejected the claims 1, 3, 5, 8-14, 20, 28, 30, 32, 35-39, 41, 43, and 46-49 under 35 U.S.C. §102(b) as anticipated by Benn.

In the Office Action when referencing the disclosure of Benn, the examiner states (emphasis added): *"expanding the bag to a non-relaxed volume in vacuum chamber 22, while subjecting the exterior, interior and the fluid to a pre-determined pressure range...."* A further reading of Benn shows that there is minimal description of the structure of Chamber 22, consisting mainly of a single sentence and a schematic drawing showing a separate chamber which is "evacuated partially to allow expansion of bag 20". This would imply that in Benn there is a separate and distinct vacuum chamber. It is precisely the fact Benn has a separate and distinct vacuum chamber that differentiates Benn from the Applicant's claimed invention as exemplified by the currently amended claims. The separate vacuum chamber of Benn does not allow for utilizing a portion of the container to form the bounds of the vacuum chamber, and there is no disclosure in Benn alluding to such a structure or method. In contrast, Claims 1, 28, and 39 as now amended, require the rigid portion of the container to seal a portion of the pressure chamber. The rigid portion sealing the bounds of the chamber, as now exemplified by the currently amended claims, has the additional benefit of allowing the manufacturer of the device to utilize a relatively simple retention fixture with only a single depression (*as shown in applicant's Figure 7 and 8 below, reproduced for the examiner's convenience*). The manufacturer is thusly able to eliminate the large two piece pressure chamber with a single fixture having only a slight depression, due to the fact that the container itself forms a portion of the pressure chamber.

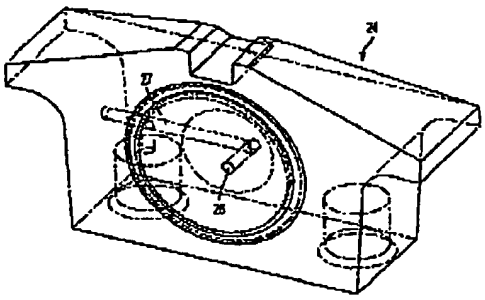

FIG. 7

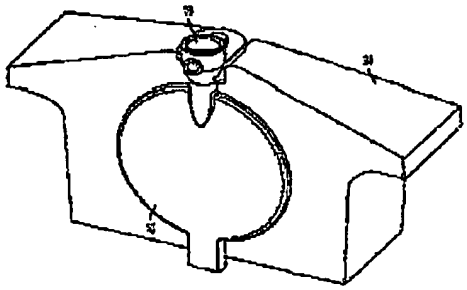

FIG. 8

In summary, even if Benn performed all the functions recited in Claims 1, 28, and 39 the device and method of Benn cannot anticipate the claim if there is any structural difference. (See MPEP § 2114 and *In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999)*). Furthermore, to support a rejection of a claim under 35 U.S.C. § 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. The device and method of Benn all have fully enclosed pressure chambers, and do not describe the applicant's structure or method. Thus, Applicant submits that currently amended Claims 1, 28, and 39 and their dependant claims are allowable over Benn since the structure and method of Benn is different from the Applicant's claimed invention.

Claim Rejections under 35 USC 103

In the Office Action, the Examiner has rejected the Claims 1, 3, 5, 8-14, 20, 28, 30, 32, 35-39, 41, 43, and 46-49 under 35 U.S.C. §103(a) as unpatentable over Benn in view of White. Furthermore, the Examiner has rejected the Claims 14, 15-19, 21, 22, 31 and 42 under 35 U.S.C. §103(a) as unpatentable over Benn alone.

White teaches a similar vacuum chamber to that of Benn. The combination of Benn and White do not produce or suggest the claimed invention, as the vacuum chamber is separate and distinct from the container. A combination of the teachings of Benn and White produces a method/device which has a different structure of the vacuum chamber. The combination of Benn and White do not produce the claimed invention, as the resultant combination produces a separate and distinct pressurizable chamber with a selection of pressure to prevent boiling of the liquid. Moreover, the combination of Benn and White do not teach or suggest using a rigid portion of the container as a portion of the vacuum chamber. In fact, neither reference teaches any relation the specific structure of the pressurizable chamber. In contrast, the claimed invention requires at least a portion the rigid portion of the container to seal a portion of the pressure chamber. For the reasons stated above, the modification of Benn alone or Benn in combination with White do not produce the instant invention as claimed. Reconsideration and allowance of Claims 1, 3, 5, 8-22, 28, 30-32, 35-39, 41-43, and 46-49 is respectfully requested.

Claims 2, 6, 29, 33, 40 and 44 are rejected under 35 U.S.C. §103(a) as being unpatentable over Benn in view of Weiler. Weiler teaches a method and device which is a variation of what is commonly known as "Form-Fill-Seal" or "Blow-Fill-Seal." Most notably different from the applicant's invention as claimed is that the BFS process requires a complete chamber, which forms a mold for the container formation, as shown in Weiler. Therefore, the retention features of Weiler fully enclose the container and serve as the mold for the production of the container of Weiler, which has a fixed volume. From the structure and description of Weiler, Weiler would be unable to form a pressure chamber using the container as a portion of the chmber. Weiler does not teach or suggest application of pressures on the exterior surface of the container, as the pressures on the outside surface of the container are limited by its contact with the mold. The combination of Benn and Weiler do not produce the claimed invention, as the pressure chamber is not formed by a portion of the container. A combination of the teachings of Benn and Weiler produces a method/device which has a different pressure chamber structure. Furthermore, the combination of Benn and Weiler do not produce the claimed invention, as the resultant combination produces a container with a static volume which is not adaptable to the volume of the fluid dispensed, and produces a fixed volume container. The claims as now amended have specific structural limitations to the pressure chamber which are not taught or suggested by Benn, White, Weiler or any combination of them. For the reasons stated above, the modification and/or combination of Benn, White and Weiler do not produce the instant invention as claimed. Reconsideration and allowance of Claims 2, 6, 29, 33, 40 and 44 is respectfully requested.

Claims 7, 34 and 45 are rejected under 35 U.S.C. §103(a) as being unpatentable over Benn and Weiler in view of Shaw. The Applicant contends that Claims 1, 28, and 45 as now presently amended distinguishes over Benn and Weiler in view of Shaw and the rejection is respectfully traversed. In view of the amendments to Claim 1 and the differences between the cited references and the claimed invention discussed above, Applicants believe this rejection is now moot. Reconsideration and allowance of Claims 7, 34 and 35 is respectfully requested.

Claims 23-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Benn in view of Green. The Applicant contends that claim 1 as now presently amended and dependent claim 23-26 distinguishes over Benn in view of Green and the rejection is respectfully traversed. In view of the amendments to Claim 1 and the differences between the cited references and the claimed invention discussed above, Applicants believe this rejection is now moot. Reconsideration and allowance of Claims 23-26 is respectfully requested.

New Claims

New claims 50-55 have been added to further define aspects of the invention, which are fully supported by the instant specification. Accordingly, no new matter has been added. For all of the reasons discussed previously, none of the references, alone or in combination, teach or suggest a method of filling and sealing containers with at least one rigid component with a pressurizable chamber having at least a portion of the chamber formed by the rigid portion and at least one flexible component in the steps outlined. Without discussing each in detail, it will be appreciated that the claims depending from Claim 50 recite additional features that are not taught or suggested by the references cited by the Examiner.

Conclusion

In view of the Remarks above, applicant respectfully submits that Claims 1-4, 6-26, 28-42, 44-46 and 49-55 are in condition for allowance, and respectfully requests that the Examiner earnestly reconsider his rejections of the present application. Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response, Request for Continued Examination (RCE), and any extensions of time and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

By: _____

Dated: September 30, 2005.

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